



State of Georgia Drugs and Narcotics Agency

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**C. Richard “Rick” Allen, RPH
Director**

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To Who It May Concern:

Ref: Georgia State Board of Pharmacy (Board) Requirements for Office Use
Drug Compounding

Pursuant to the new FDA requirements for pharmacies compounding drugs for sale to practitioners for Office Use, as of October 1, 2015, any and all pharmacies compounding drugs for Office Use must be registered with the FDA as a Drug Compounding Outsourcing Facility under Section 503B of the Food, Drug, and Cosmetic Act. This law supersedes current Georgia law and Board rules. Changes will need to be made in both the law and Board rules to align Georgia with the FDA requirements.

If you are receiving this letter, you previously notified the Board that you would be compounding drugs for Office Use, and you are aware that previously Georgia law and rules allowed Office Use drug compounding. However due to the new FDA Outsourcing Facility 503B restrictions, which are stricter and override the less restrictive Georgia law and rules, you can no longer legally compound drugs for Office Use unless you are registered with the FDA as a 503B Outsourcing Facility.

If a pharmacy is merely compounding drugs to fill patient specific prescriptions for dispensing to patients in Georgia, you do not have to register as a 503B outsourcing facility. You are what the FDA considers a 503A facility. You still have to follow Georgia laws and rules for compounding. Your existing Georgia pharmacy license (either in-state or non-resident) will suffice, and you do not need any other Georgia license, nor do you need any FDA registration.

After October 1st, 2015 any and all Office Use compounded drug products distributed to Georgia practitioners by non-registered FDA Drug Compounding Outsourcing Facilities are subject to seizure by this agency and/or the FDA as misbranded drug products.

To clarify:

In order for any Georgia licensed in-state or non-resident pharmacy to compound human drugs for Office Use distribution to a Georgia practitioner or pharmacy, that compounding pharmacy/facility must be registered with the FDA as an Outsourcing Facility and meet the requirements of Section 503B of the FD&C Act.

- 503B Outsourcing Facilities Requirements for Office Use Drug Compounding
 - The facility must be conducting some sterile compounding and comply with 503B regulations to qualify for 503B registration. If the facility is not conducting sterile compounding, it does not qualify for a 503B registration.
 - The facility can also conduct non-sterile compounding and fill standard prescriptions
 - ALL prescription medications, both sterile and non-sterile, must be prepared under current Good Manufacturing Practice (cGMP) standards as well as the Georgia Board Rule for Compounding, 480-11, which require the USP 797 and 795 compounding requirements.
 - Georgia requires all 503B outsourcing facilities to be a licensed pharmacy, both in-state and non-resident, and all compounding must be by or under the direct supervision of a licensed pharmacist.
 - **Georgia requires that all 503B outsourcing facilities also hold a Georgia drug manufacturing permit as well as the pharmacy permit.**
 - 503B outsourcing facilities can dispense patient specific prescriptions to patients
 - 503B outsourcing facilities can distribute non-patient specific medications to facilities, i.e. Office Use to practitioners.
 - 503B outsourcing facilities may not sell the Office Use drug to another entity for resale. It is intended to go to the patient or to be administered within a healthcare setting.
 - Annual registration fee of \$15,000 paid to the FDA. If the FDA inspects a facility and must re-inspect due to deficiencies, the facility will pay the FDA an additional \$15,000 inspection fee.

What this means:

For any pharmacy that compounds drugs for Office Use: Per the FDA Outsourcing Facility 503B requirements you can no longer compound either non-sterile or sterile drug products to distribute for Office Use to Georgia practitioners unless you register with the FDA as an Outsourcing Facility. **If you do register as an Outsourcing Facility, you will need to maintain your Georgia pharmacy license as well as obtain a Georgia Drug Manufacturing license.**

For FDA Information:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm>

Any questions, please contact either GDNA Deputy Director Dennis Troughton or me.

Sincerely,



Rick Allen, RPH, Director